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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,288	05/09/2002	Paolo Pevarello	218195USOPCT	9829
7590	01/31/2006			
PETER BERNSTEIN SCULLY, SCOTT, MURPHY & PRESSER 400 GARDEN CITY PLAZA GARDEN CITY, NY 11530			EXAMINER ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 01/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/049,288	<b>Applicant(s)</b> PEVARELLO ET AL.	
	<b>Examiner</b> Rebecca L. Anderson	<b>Art Unit</b> 1626	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 19 September 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 16 December 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: \_\_\_\_\_.
- Claim(s) objected to: \_\_\_\_\_.
- Claim(s) rejected: \_\_\_\_\_.
- Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.


#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_
13. ☐ Other: \_\_\_\_\_.

**KAMAL A. SAEED, PH.D.**  
**PRIMARY EXAMINER**

*[Signature]*

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the R as C3-6cycloalkyl is not new matter due to support found in preferred embodiments and due to the SAR methodology, however this argument is not persuasive for essentially the same reasons as found in the final office action. Specifically, the examiner has not argued that R cannot ever be a C3-6 cycloalkyl, just that there is not support for R as C3-6cycloalkyl in the generic compound claimed, i.e. R can be C3-C6 cycloalkyl when n is 0 and R2 is hydrogen, but there is no support found in the originally filed disclosure for R to be C3-6 cycloalkyl when n is not 0 and R2 is not hydrogen, as instantly claimed. The specific species found in the specification only provide support for themselves, and the preferences only support R as C3-C6 cycloalkyl when n is 0 and R2 is hydrogen. One of ordinary skill in the art would not recognize the existence of an error or the appropriate correction. Therefore, as previously argued in the final office action, the originally filed disclosure does not provide support for R as C3-6cycloalkyl when n is 1-4 and/or R1 and R2 together with the nitrogen atom form a heterocycle or heteroaryl. In regards to the 35 USC 112 1st paragraph enablement rejection, applicant argues that the specification provides sufficient support for the enablement of the instant claims. However, this argument is not persuasive as claim 1 still includes diseases such as HIV and Alzheimer's disease. Furthermore, the treatment of cancer is not a reasonable correlation to the entire scope of claim 1 as treating any cell proliferative disorder. Lastly, the broad treatment of cancer does not find enablement in the instant specification as it is known in the prior art that cancer therapy remains highly unpredictable, that tumors with similar histopathological appearance can follow significantly different clinical courses and show different responses to therapy, that treatment against tumors with rapidly dividing cells can differ from the treatment of solid tumors with relatively slow dividing cells and that both the promotion and inhibition of NO is mentioned for the treatment of tumor progression and only certain human cancers may be treated by selected NO-blocking drugs. Since the cancer therapy is highly unpredictable, one of ordinary skill in the art would not accept any therapeutic regimen on its face and there is a more specific enablement necessary in order to satisfy the statute. Furthermore, there is no support found in the instant application for the treatment of cancer, i.e. there is no direction or guidance or working examples to show the treatment of any and all cancers with applicants' instant formulas (I). Therefore, the objection to the specification is maintained and the claim rejections are maintained.

  
KAMAL A. SAEED, PH.D.  
PRIMARY EXAMINER